IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KIMBERLY GREMO, Plaintiff, v. BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., GE HEALTHCARE, INC, GENERAL ELECTRIC COMPANY, MALLINCKRODT, INC., MALLINCKRODT LLC, GUERBERT LLC, LIEBEL-FLARSHEIM COMPANY LLC, AMERISOURCE BERGEN CORPORATION, and AMERISOURCE BERGEN DRUG CORPORATION Defendants.	CASE NO. 1:19-cv-13432-NLH-AMD

DEFENDANTS MALLINCKRODT INC. AND MALLINCKRODT LLC'S MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

Defendants Mallinckrodt Inc. and Mallinckrodt LLC (collectively, "Mallinckrodt"), by and through counsel, respectfully submit this Memorandum in Support of Their Motion to Dismiss the claims asserted in Plaintiff Kimberly Gremo's Amended Complaint (Doc. 62), for failure to comply with the pleading requirements of Fed. R. Civ. P. 8(a) and failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Rules

I. INTRODUCTION

Plaintiff's Amended Complaint does not cure the fatal deficiencies of her original pleading.[1] First, Plaintiff still fails to plead sufficient facts to show that her claims are not preempted. Plaintiff contends that Mallinckrodt should have added a warning to OptiMARK's label stating that gadolinium retention from OptiMARK™ posed health risks for persons like Plaintiff with normal renal function. But this contention fails because Plaintiff improperly relies on conduct that occurred prior to FDA's approval of OptiMARK's initial label, and pleads no facts showing Mallinckrodt could have independently changed its product label without FDA's prior approval. Moreover, the publically available FDA documents incorporated into the Amended Complaint show that, even if Mallinckrodt had attempted to make Plaintiff's requested change, the FDA would have rejected it. Second, Plaintiff's claims fail because her Amended Complaint contains no facts demonstrating that her alleged injuries were reasonably foreseeable. Without such facts, Plaintiff cannot state a viable inadequate warning claim. Third, Plaintiff's breach of express warranty

[1] Mallinckrodt filed a motion to dismiss Plaintiff's original complaint on August 2, 2019 (Doc. 52). Plaintiff subsequently filed an Amended Complaint on August 20, 2019 (Doc. 62). Plaintiff has abandoned her claims for manufacturing defect, negligence, breach of implied warranty, negligent misrepresentation, fraudulent misrepresentation, and consumer fraud. *See generally* Am. Compl. However, as set forth herein, Plaintiff's Amended Complaint does not cure the remaining deficiencies identified in Mallinckrodt's motion to dismiss, and dismissal is still appropriate.

claim fails because Plaintiff did not provide the requisite pre-suit notice and failed to plead necessary facts regarding the purported warranty. Finally, Plaintiff's prayer for punitive damages fails as a matter of law.

II. THE MOTION TO DISMISS STANDARD

Pursuant to the Federal Rules of Civil Procedure, a complaint must set forth a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). To survive a motion to dismiss, a complaint must contain more than "naked assertions," "labels and conclusions," or "a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-57 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Rather, the plaintiff must allege facts that, if accepted as true, are sufficient "to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 557, and to "state a claim to relief that is plausible on its face." *Id.* at 570.

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "[U]nsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations" do not meet this standard. *Continental Insurance Co. of New Jersey v.*

United States, 335 F.Supp.2d 532, 534 (D.N.J. 2004) (citing *Miree v. DeKalb County, Ga.*, 433 U.S. 25 (1977)).

A court should evaluate factual allegations to determine whether "they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679. While courts should accept all factual allegations as true, courts are not required to accept as true "a legal conclusion couched as a factual allegation." *Id.* at 678. A complaint that does not meet the plausibility standard cannot survive a motion to dismiss. "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency…should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (internal citations omitted) (ellipses in original). This standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 566 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.*

III. ARGUMENT

A. Plaintiff's Claims Are Preempted.

In two recent cases where plaintiffs made the same allegations related to gadolinium-based contrast agents, federal court judges have dismissed plaintiffs' claims as preempted at the motion-to-dismiss stage. **Exhibit A**, *McGrath v. Bayer*

Healthcare Pharm., Inc., No. 18 CV 2134 (RJD) (VMS), 2019 WL 2582530 (E.D.N.Y. June 24, 2019); **Exhibit B**, *Klein v. Bayer Healthcare Pharm., Inc., et al.*, No. 2:18-cv-01424-APG-EJY, 2019 WL 3945625 (D. Nev. August 21, 2019). Plaintiff's Amended Complaint, which presents scientific allegations that largely copy the allegations from the *McGrath* and *Klein* complaints, has the same deficiency: Plaintiff fails to plead facts showing Mallinckrodt could have changed OptiMARK's label at any time to include her desired warning that gadolinium retention causes the injuries she claims in persons with normal kidney function. That means Plaintiff's warning-based claims, including failure to warn (Count I) and breach of express warranty (Count III), are preempted under federal law. Plaintiff's design defect claim (Count II) is preempted, as well.

Plaintiff's Amended Complaint fails to meet numerous requirements necessary to avoid preemption. First, a plaintiff cannot object to a label based on conduct arising before the FDA approves that label—for example by claiming the defendant should have given the FDA more information to decide whether to approve the label. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 36 (1st Cir. 2015). Second, the plaintiff must show that the defendant could unilaterally change the label after initial FDA approval of the label by alleging that the defendant possessed "newly acquired information" unknown to the FDA when it approved the

label. *See Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707–09 (2d Cir. 2019); *Byrd v. Janssen Pharm., Inc.*, 333 F. Supp. 3d 111, 120 (N.D.N.Y. 2018); *In re Celexa*, 779 F.3d at 41-42. Third, even where the defendant had newly acquired information permitting unilateral label change, a plaintiff's claim is still preempted upon "clear evidence" that the FDA would have rejected the defendant's unilateral label change. *See, e.g., Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 720 (3rd Cir. 2018). Finally, Plaintiff's design defect claims are preempted, as well. There is no way Mallinckrodt could have made changes to OptiMARK's formulation given the regulatory bar on a manufacturer's unilateral alteration of a drug's design. See 21 C.F.R. § 314.70(b)(2)(i); *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 477 (2013).

Since Plaintiff fails all these requirements for avoiding preemption, her claims should be dismissed at the motion-to-dismiss stage—a juncture where courts often dismiss preempted claims. *See* **Ex. A**, *McGrath*, 2019 WL 2582530 (dismissing preempted claims relating to exposure to an FDA-approved gadolinium-based contrast agent); **Ex. B,** *Klein*, 2019 WL 3945625 (same). *See also Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672-73 (S.D.N.Y. 2017) ("It is well-established that preemption may be analyzed and decided at the motion to dismiss stage."); *In re Celexa*, 779 F.3d at 43 (holding pharmaceutical drug claims preempted at motion-to-dismiss stage); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624

(2011) (same); *Gibbons*, 919 F.3d at 699 (upholding trial court's grant of motion to dismiss on preemption grounds).

1. Plaintiff's Claims Are Preempted to the Extent Plaintiff Alleges that Mallinckrodt Failed to Communicate Information to the FDA Before Approval of OptiMARK's Initial Label.

Plaintiff cannot rely on any allegations that Mallinckrodt failed to inform the FDA of information known before OptiMARK's 1999 initial approval (e.g. Am. Compl. ¶¶ 125-129), because "[f]ederal law preempts state-law claims based on a defendant's failure to communicate with the FDA." *McGee v. Boehringer Ingelheim Pharm., Inc.*, No. 4:16-CV-2082, 2018 WL 1399237, at *4 (N.D. Ala. Mar. 20, 2018). When the FDA initially approved OptiMARK™ in 1999, the agency conducted an "onerous and lengthy" process requiring Mallinckrodt to "submit the labeling proposed to be used for" OptiMARK™. *In re Celexa*, 779 F.3d at 35-36 (quotation marks omitted). The FDA approved OptiMARK's initial label, including its warning; at the time of approval, Mallinckrodt was required to distribute OptiMARK™ with precisely that label. *See id.* ("After approval, the manufacturer may distribute the drug without violating federal law as long as it uses the FDA-approved label.").

Claims that Mallinckrodt failed to inform the FDA of any risks before it approved OptiMARK's label are preempted for numerous reasons. In *Buckman*, plaintiffs claimed that a manufacturer's "fraudulent [pre-approval] representations

to the FDA" led the FDA to approve harmful products. 531 U.S. at 346-48. The United States Supreme Court held those claims were "pre-empted by [] federal law," since "the federal statutory scheme amply empowers the FDA," not private plaintiffs, "to punish and deter fraud against the [FDA]." *Id*. Accordingly, any claim "that [a defendant] should have alerted the FDA about [a] risk *before*…approval…is preempted because the claim is essentially one of failure to communicate with the FDA." *McGee*, 2018 WL 1399237, at *4 (granting motion to dismiss).

Further, Plaintiff may not claim OptiMARK's label was inadequate when approved by the FDA since Mallinckrodt could not have changed the initially-approved label unilaterally. "[W]hen a party cannot satisfy its state duties without the [FDA's] special permission and assistance," those state duties "are pre-empted." Mensing, 564 U.S. at 623-24. Because "manufacturers lack the authority to alter…a label's warnings at the time the [initial FDA] approval process concludes," "federal law preempts all…failure to warn and design defect claims" based on defendants' actions taken "pre-FDA approval."[2] Utts, 251 F. Supp. 3d at 660.

[2] Moreover, FDA approval of a drug label reflects "the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively," *Utts*, 226 F. Supp. 3d at 184, and the FDA's judgement that "the proposed label is not false or misleading in any particular." *In re Celexa*, 779 F.3d at 36 (quotation marks omitted). Claims objecting to a drug label as initially approved by the FDA thus impermissibly target the agency itself. *Utts*, 226 F. Supp. 3d at 184.

Here, Plaintiff impermissibly relies on allegations that Mallinckrodt failed to communicate information to the FDA before OptiMARK's approval, resulting in an improper initial OptiMARK™ label. *See Buckman*, 531 U.S. 341; *Utts*, 226 F. Supp. 3d at 184. Plaintiff broadly alleges that Mallinckrodt provided inadequate safety information. *See, e.g.*, Am. Compl. ¶¶ 170, 172-177. Plaintiff's argument relies on alleged scientific developments before 1999, the year of OptiMARK's approval and entry to the market. Plaintiff alleges that "medical and scientific literature have reported on the deposition of toxic gadolinium in animal tissue" *"[s]ince as early as 1984." Id.* ¶ 125 (emphasis added); *see also id.* ¶ 127 (referencing a September 1989 report revealing "a high concentration of gadolinium remained in the tissue" of a human"); ¶ 128 (claiming that "[i]n 1993…preclinical safety assessment and pharmacokinetic data were published…show[ing] quantifiable concentrations of gadolinium were persistent" in rats, rabbits, and monkeys). Plaintiff further contends that manufacturers were "aware of the evidence of gadolinium deposition in biological systems" "in 1988." *Id.* ¶ 126. Plaintiff's allegations that Mallinckrodt should have acted on information at a time before the FDA approved OptiMARK's initial label must be disregarded because that argument is preempted.

2. Plaintiff Failed to Plead "Newly Acquired Information" that Would Allow Mallinckrodt to Unilaterally Add Plaintiff's Desired Warning After OptiMARK's Approval.

Plaintiff also fails to show Mallinckrodt could have unilaterally added Plaintiff's desired warning of health risks from gadolinium retention to OptiMARK's label at any time *after* the FDA's initial approval of the product and *before* Plaintiff last used OptiMARK™—which means her claims are entirely preempted. "[W]hen a party cannot satisfy its state duties without the [FDA's] special permission and assistance," those state duties "are pre-empted." *Mensing*, 564 U.S. at 632-24. That means Plaintiff must show that "the defendants could *unilaterally* change the label without FDA approval" to escape preemption. *Byrd*, 333 F. Supp. 3d at 120 (emphasis added, ellipses omitted). And "federal law expressly forbids a manufacturer from changing its label after the label has received FDA approval unless such changes are made pursuant to the ["Changes Being Effected," or "CBE"] regulation. *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1232-34 (9th Cir. 2011) (vacated on other grounds); *Utts*, 226 F. Supp. 3d at 184-85; *Mensing*, 564 U.S. at 624 (explaining that *Wyeth v. Levine*, 555 U.S. 555 (2009), held that a failure-to-warn claim "was not pre-empted because it was possible for Wyeth…to comply with both state and federal law" using "the CBE regulation"). "The CBE procedure is only available to make changes…based on 'newly acquired information'" discovered *after* a label receives initial FDA approval. *In re Celexa*,

779 F.3d at 41-42 (emphases added). And that "new [] information" must provide "reasonable evidence of a causal association" of "a clinically significant" "adverse reaction[]" linked to a drug. *See* 21 C.F.R. § 201.57(c)(6)(i). To be "clinically significant," the adverse reaction must "have significant impact on therapeutic decisionmaking," *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006), such as a risk is "potentially fatal, [or otherwise] serious," 21 C.F.R. § 201.57(c)(6)(i). Thus, Plaintiff must allege *facts* showing that Mallinckrodt had "newly acquired information" of "clinically significant" adverse reactions linked to OptiMARK™ after FDA's initial approval in 1999 and before December 2016 – the last time Plaintiff allegedly received OptiMARK™. *See* Am. Compl. ¶164.

Plaintiff makes no such showing. The Amended Complaint recites nothing more than non-specific, boilerplate phrases targeted at avoiding preemption. *See, e.g.*, Am. Compl. ¶ 155 ("At all times following the respective FDA approvals of their products and before Plaintiffs' injuries, Defendants…had, or should have had, 'newly acquired information' sufficient to warrant product labeling changes to warn about the risk of gadolinium retention and consequent injury, including but not limited to new data, new analysis of old data, data taking on a new meaning in light of subsequent developments and/or a new understanding of the type, severity, or frequency of the risk at issue."); ¶ 163 ("At all times relevant to this action,

Defendants could have changed their product labeling to both comply with New Jersey tort law and in a way as to not run afoul of FDA regulations or other federal law."). However, Plaintiff's allegations amount to nothing more than "naked assertions," "labels and conclusions," and "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555-557; *see also Iqbal*, 556 U.S. at 679 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice."). The "facts" Plaintiff includes in her Amended Complaint fall far short of showing Mallinckrodt could have met the CBE standard to add Plaintiff's desired warning to OptiMARK's label:

- Most of Plaintiff's listed scientific developments relate to mere *retention* of trace amounts of gadolinium in patients' bodies after using GBCAs—not to any further adverse reaction caused by retention, *see* 21 C.F.R. ¶ 201.57(c)(6)(i), much less a "clinically significant" one with "significant impact on therapeutic decision making," *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006). *See, e.g.*, Am. Compl. ¶¶ 125-131, 133-134, 156(a)-(f), (k), (p), (x). *See also* **Ex. A**, *McGrath*, 2019 WL 2582530, at *4 ("Because Plaintiff's failure-to-warn claims depend upon Bayer's failure to warn of the *risks* of gadolinium retention, plausible allegations that relate only to the *fact* of gadolinium retention do not suffice.").

- Plaintiff references other scientific developments and regulatory actions that occurred either *before* FDA's initial approval of OptiMARK™ in 1999 or *after* Plaintiff last used OptiMARK™ in December 2016. *See*, e.g., Am. Compl. ¶¶ 108, 121, 123, 127, 156(l), (n)-(p), 157 (citing studies published in 1988, 1989, 1991, 1996, 2017, and 2018); ¶¶ 137-150 (referencing regulatory actions that occurred in 2017 and 2018).

- Other developments relate to general facts about GBCAs, have nothing to do with any purported direct effects on humans, or relate to side effects not

alleged by Plaintiff in this case. *See, e.g.*, Am. Compl. ¶¶ 90-110 (commenting on the structure, strength, and stability of gadolinium chelates); ¶¶ 125, 128, 156(n)-(o), (q), (bb)-(cc) (discussing deposition of gadolinium in animals); ¶¶ 156(q)-(s), (z) (discussing perinatal exposure, accidental intrathecal injections, and side effects including seizures, vegetative state, and difficulty breathing). *Compare to id.* ¶¶ 167 (alleging injuries including rashes, dermatitis, burning, hyperpigmentation, rough patches, loss of elasticity, peeling and callus like buildup, darkened teeth and spots, cracking teeth, and teeth sensitivity, brain fog and memory loss, hip pain, back pain, bone pain, and joint pain, neuropathy, fatigue, muscle aches fasciculation, and loss of smell).

- Plaintiff also extensively discusses nephrogenic systemic fibrosis (NSF), which is not relevant to her lawsuit premised on her normal kidney function since NSF affects only persons with kidney impairments. *See, e.g.*, Am. Compl. ¶¶ 111-124, 156(q), (t), (x)-(y), 159.3

---

[3] Plaintiff attempts to relate NSF to the current litigation by positing that GBCAs cause a "continuum" of symptoms, the most severe of which constitute NSF and the less severe of which are commonly seen in "gadolinium toxicity" or "gadolinium deposition disease." *See, e.g.*, Am. Compl. ¶ 124. In support, Plaintiff cites to testimony from Dr. Pierre Desche and Dr. Gene Williams. *Id.* ¶ 147-48. However, a federal court judge has already reviewed this cited testimony and determined that it has been misinterpreted, if not intentionally misconstrued, by Plaintiff:

> The continuum Dr. Desche mentions is from gadolinium retention to gadolinium toxicity causing NSF. He does not say there is a continuum that includes a wide range of milder symptoms that encompass [gadolinium deposition disease]…Dr. Williams suggests that there "might" be a continuum detected if the varying degrees of renal impairment could be separated. And he is talking about the universe of patients with renal impairment, not individuals like Plaintiff[] who have no renal impairment. Even then, the most he says is that there "might" be a continuum and it is "a reasonable idea." He does not endorse [Plaintiff's] continuum conclusion.

Exhibit C, *Davis v. McKesson Corp. et al.*, No. 2:18-cv-01157-DGC, Dkt. No. 217 at 21-22 (D. Ariz. Aug. 2, 2019). Moreover, the *Davis* Court has reviewed the

- The remaining "facts" are unsupported generalizations that on their face fail the pleading requirements of *Iqbal*, 556 U.S. at 679 ("legal conclusions…must be supported by…well-pleaded factual allegations"). *See*, *e.g.*, Am. Compl. ¶ 156(g) ("Pathological and/or clinical consequences from GBCA exposure, such as skin changes, have been reported in patients with normal renal function."); ¶ 156(h) ("Adverse events associated with GBCAs and involving multiple organ systems have been reported in patients with normal renal function.").

Stripping the Amended Complaint of its formulaic recitation of legal elements and irrelevant "facts," Plaintiff is left with nothing demonstrating that Mallinckrodt had newly acquired information of clinically significant adverse reactions linked to OptiMARK™ at any time, let alone the time period at issue in this case. *See* **Ex. A**, *McGrath*, 2019 WL 2582530, at *4 ("[I]t helps precious little to mount scientific minutiae on top of technical jargon if that information ultimately does not plead a causal association between [OptiMARK] and adverse effects.").

The fact that Plaintiff's Amended Complaint is completely devoid of this necessary factual underpinning is unsurprising, as the FDA's repeated, emphatic statements about GBCAs show that there has never been "information" demonstrating a "clinically significant" "adverse reaction[]" that would allow Mallinckrodt to add Plaintiff's desired warning. In 2018, the FDA approved

---

entirety of expert evidence plaintiffs have previously proferred on this issue and determined that plaintiffs "have not shown by a preponderance of the evidence that the continuum theory…is the product of reliable principles and methods applied reliably." *Id.* at 26.

OptiMARK's current label stating that "adverse events…have been reported in patients with normal renal function *without an established causal link to gadolinium retention.*"[4] That statement is consistent with the FDA's prior public statements that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function."[5] Moreover, a federal court judge has already examined the entirety of the evidence and determined that there is no reliable expert evidence available to support the conclusion that gadolinium retention is causally related to adverse events in patients with normal renal function. See **Ex. C**, *Davis*, No. 2:18-cv-01157-DGC at 21-22; *see also* **Ex. A**, *McGrath*, 2019 WL 2582530, at *4 ("To date, the incidence of any *risks* associated with gadolinium retention is inconclusive and is, at best, only marginally supported by data gathered *after* Plaintiff's [gadolinium] injections.").

Plaintiff thus fails to plead failure-to-warn and breach-of-warranty claims against Mallinckrodt can escape preemption. Accordingly, these claims should be dismissed. *See Utts*, 226 F. Supp. 3d at 184-85 (dismissing claims as preempted); *In re Celexa*, 779 F.3d at 43 (affirming dismissal where claims were preempted).

---

[4] *See* **Exhibit D**, 04/2018 Revised OptiMARK™ Label at p. 14 (emphasis added).

[5] *See* **Exhibit E**, 12/19/17 FDA Safety Announcement; *see also* **Exhibit F**, 07/27/2015 FDA Drug Safety Communication (stating that, while "trace amounts of gadolinium may stay in the body long-term," the "[a]vailable information does not identify any adverse health effects.").

3. Plaintiff Failed to Allege Facts Showing that the FDA Lacked Any Information Pleaded in the Complaint.

Plaintiff also fails to plead facts showing that any new information pertinent to her alleged injuries was unknown by the FDA, which is another independent reason her claims are preempted as pled. Mallinckrodt can only change OptiMARK's label based on "newly acquired information, as th[at] term is defined in 21 C.F.R. § 314.3(b)." *See Gibbons*, 919 F.3d at 708. And "newly acquired information" must "reveal[] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." *Id*. (quoting 21 C.F.R. § 314.3(b)); *see also* **Ex. A**, *McGrath*, 2019 WL 2582530 at *3 ("Newly acquired information" is limited to "information not previously submitted to the FDA"). In *Gibbons*, the Second Circuit affirmed the dismissal of the plaintiff's complaint that "provide[d] no basis upon which the court could conclude that" any alleged new information "presented a different type of risk than those the company had discussed with the FDA, or [any risk] more severe or more frequent than . . . [those] the government already knew about." *Gibbons*, 919 F.3d at 708.

In this case, Plaintiff similarly pleads nothing to show that any "new[] . . . information" alleged in the Amended Complaint was different from what the FDA previously knew or what Mallinckrodt had discussed with the agency. In fact, Plaintiff's Amended Complaint demonstrates that the FDA was well aware of the "information" pertinent to her alleged injuries:

> [I]n 2017, the FDA began evaluating concerns of gadolinium retention, completing an examination of gadolinium accumulation in individuals with normal kidney function and confirmed GBCA exposure. Specifically, the FDA evaluated adverse event reports ("AERs") in 139 patients (41 cases in its adverse event reporting database and 98 cases in the medical literature reported since 1988) in conjunction with gadolinium retention after GBCAs…FDA's analysis of cases identified consistent clustering around cutaneous, musculoskeletal, cognitive/neurological, and pain syndrome clinical categories following exposure to GBCAs.

Am. Compl. ¶¶ 142-44; *see also id.* ¶ 132 ("By 2012, some patients were sending letters to the FDA to describe the occurrence of gadolinium toxicity in patients with normal renal function following injections of GBCAs."). Moreover, the FDA's safety announcements *specifically cite* studies listed in Plaintiff's Amended Complaint while concluding that "[a]vailable information does not identify any adverse health effects" from GBCAs in patients with normal kidney function. *See* **Ex. F**, 07/27/2015 FDA Safety Announcement (citing McDonald and Kanda articles cited in Plaintiff's Amended Complaint ¶¶ 120, 133-34, and 156(k)). Since Plaintiff fails to plead facts showing that the FDA lacked any of the purported scientific information referenced in the Amended Complaint, Plaintiff pleads no "newly acquired information" that could have justified Mallinckrodt revising the OptiMARK™ label through the CBE regulation, and her claims are preempted for that independent reason.

4. Clear Evidence Shows the FDA Would Have Rejected Plaintiff's Desired Warning Had Mallinckrodt Added It Using the CBE Regulation.

Even if Plaintiff had pled that Mallinckrodt could have changed OptiMARK's label using the CBE regulation, which she has not, she still failed to plead facts showing that the FDA would have allowed the labeling change she seeks, so her claims are preempted nonetheless. *See, e.g., Dolin v. GlaxoSmithKline LLC,* 901 F.3d 803, 812 (7th Cir. 2018) ("[E]ven if GSK had newly acquired information [satisfying the CBE regulations], GSK can still succeed on its preemption defense if there is clear evidence that the FDA would have rejected the…warning…"). Though manufacturers can change label text unilaterally with the CBE regulation, "the FDA can [later] reject CBE submissions and require manufacturers to revert to the prior version of the label." *Id*. A tort claim requiring a label change is preempted if "there [is] clear evidence the FDA would have rejected the proposed change in the drug's label." *See id.; Cerveny v. Aventis, Inc.,* 855 F.3d 1091, 1098 (10th Cir. 2017) (similar).

Here, the Amended Complaint and associated materials provide clear evidence that the FDA would have rejected Plaintiff's desired label change: the FDA approved a label explicitly denying that scientific evidence demonstrated any clinical consequences from the gadolinium retention Plaintiff claims. Specifically, in 2017, the FDA convened its Medical Imaging Drugs Advisory Committee

("MIDAC") to discuss "the potential risk of gadolinium retention in the brain and other body organs in patients receiving gadolinium-based contrast agents." *See* **Exhibit G**, 08/18/2017 FDA Public Participation Information, Meeting of the MIDAC at 1; *see also* Am. Compl. ¶ 146 (noting September 2017 meeting). MIDAC received briefing and testimony from leading experts, as well as any members of the public wishing to comment. *Id.*

After hearing the evidence, the FDA approved a revised OptiMARK™ label in April 2018 stating that "adverse events…have been reported in patients with normal renal function *without an established causal link to gadolinium retention.*" **Exhibit D**, 04/2018 Revised OptiMARK™ Label at 14. The FDA's approval of this label—after thorough consideration of the very issue Plaintiff claims should have been included—is clear evidence that the FDA would have rejected Plaintiff's proposed warning. *See Cerveny*, 855 F.3d at 1099, 1101-02 (holding that "FDA's rejection of [a] citizen petition" requesting a warning, based on the agency's "evaluat[ion of] the scientific merit" of the request and "survey [of] the literature" relevant to the question, was "clear evidence" that the FDA would not have approved the requested warning); *Risperdal and Invega Prod. Liab. Cases*, No. BC599531, 2017 WL 4100102, at *10 (Cal. Super. Ct. Mar. 16, 2017) ("The denial of the Citizens Petition…alone also serves to provide 'clear evidence' that the FDA was satisfied with the current…label…"). That is particularly so because the FDA's

approval of OptiMARK's 2018 label reflected "the agency's formal, authoritative conclusions regarding the conditions under which [OptiMARK™] can be used safely and effectively," *Utts*, 226 F. Supp. 3d at 184, and required the agency to conclude "that [OptiMARK's label was] not 'false or misleading in any particular." *In re Celexa*, 779 F.3d at 36. Since clear evidence shows the FDA would have rejected Plaintiff's desired warnings, Plaintiff's failure to warn and breach of warranty claims are preempted on this additional ground.[6]

Moreover, "Congress has imposed on the FDA a duty to initiate a label change if the [agency] becomes aware of new information, including any new safety information[,] that the [agency] determines should be included in the labeling of the drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1675-76 (2019) (Alito, J., concurring) (internal quotation and ellipsis omitted) (quoting 21 U.S.C. § 355(o)(4)(A)). Given that the FDA "decline[d] to require [Plaintiff's desired] label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *See id*. In light of the FDA's duty to initiate label changes where necessary, and its

[6] In her Amended Complaint, Plaintiff appears to suggest that the FDA would not have rejected Plaintiff's proposed label change because Guerbet sought a labeling change in 2016, which was subsequently approved by the FDA. *See, e.g.*, Am. Compl. ¶ 152. However, Guerbet's 2016 label change relates only to gadolinium *retention*, and explicitly states that "the clinical significance of gadolinium retention in the body and brain is otherwise unknown." *Id.*

review of voluminous information and statements on this issue, its decision to approve the current labeling further shows "clear evidence" that Plaintiff's proposed contrary label would have been rejected, which means Plaintiff's claims are preempted.

5. Plaintiff's Design Defect Claims Are Preempted by Federal Law.

Plaintiff's design defect claims are also preempted. *See, e.g.,* Am. Compl. ¶¶ 183-205. "Once a drug . . . is approved, the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Bartlett*, 570 U.S. at 477 (quotation marks omitted). Plaintiff makes no argument—and there is none—for how Mallinckrodt could have made unilateral changes to OptiMARK's formulation given the regulatory bar on altering a drug's design. *See* 21 C.F.R. § 314.70(b)(2)(i). No prescription-drug manufacturer can change an approved product's design "independently" or "unilaterally," *i.e.*, without prior FDA approval. *Bartlett*, 570 U.S. at 477. Were a manufacturer to do so, "the altered chemical would be a new drug" requiring new FDA approval. *Id*. at 484. Because Mallinckrodt cannot "independently" change FDA-approved product formulations—and indeed is flatly prohibited from doing so—Plaintiff's design-related claims are preempted. *See id.; see also Yates v. Ortho-McNeil-Janssen*, 808 F.3d 281 (6th Cir. 2015). Nor can Plaintiff argue that Mallinckrodt should have

stopped selling OptiMARK™, an FDA-approved drug, because of alleged risks. *See Bartlett*, 570 U.S. at 488 (describing a "stop-selling" requirement as "incompatible with our pre-emption jurisprudence.").

B. Plaintiff's Amended Complaint Does Not Comply with Rule 8(a) and Must be Dismissed.

Plaintiff's 224-paragraph Amended Complaint pleads only eleven substantive allegations against any of the eleven individual defendants. See Am. Compl. ¶¶ 85, 126, 138, 140, 152, 154-55, 157, 169, 184, and 192.[7] This Court has consistently ruled that pleadings that fail to explain who committed what actions are impermissibly vague and fail to comply with the pleading standards set out by Rule 8(a). Transportation Insurance Co. v. Am. Harvest Baking Co., Inc., No. CV 15-663, 2015 WL 9049273, at *8 (D.N.J. Dec. 16, 2015) (collecting cases). See also Galicki v. New Jersey, No. CIV.A. 14-169, 2015 WL 3970297, at *2 (D.N.J. June 29, 2015) ("Plaintiffs provide only conclusory allegations against Defendants as a group, failing to allege the personal involvement of any Defendant as is required."). Beginning at Paragraph 83, nearly all of Plaintiff's substantive allegations are collectively made against "Defendants." See generally Am. Compl. ¶¶ 83-224. She makes not even a cursory effort to distinguish between the roles or specific actions of the various defendants over the nearly 10 years that she alleges she used three

[7] 82 concern jurisdiction and venue. *See* Am. Compl. ¶¶ 1-82.

different products. See Am. Compl. ¶ 164. Because Plaintiff's Amended Complaint fails to identify the specific conduct of any defendant, it does not comply with Rule 8(a) and should be dismissed.

C. Plaintiff's Amended Complaint Does Not Comply with Rule 12(b)(6) and Must be Dismissed.

1. Plaintiff Fails to Assert Facts Sufficient to State a Plausible Failure-to-Warn Claim.

Plaintiff's failure-to-warn claim (Count I) should also be dismissed because Plaintiff has not pled facts sufficient to satisfy federal pleading standards. In order to state a viable failure-to-warn claim under New Jersey law, Plaintiff must plead facts showing that the manufacturer failed to warn of a *foreseeable* danger. *See, e.g.*, New Jersey Model Jury Charge (Civil) § 5.40C ("If [Defendant] proves that the danger in question was not knowable by it at the time of manufacture or sale, then it had no duty to warn of the danger and cannot be held liable for failure to do so…A duty to warn arises if [Defendant] (the manufacturer/seller) actually knew or should have known of the need to issue a particular warning.").

Plaintiff pleads no *facts* to suggest that Mallinckrodt had the requisite knowledge that gadolinium retention from OptiMARK™ posed an unreasonable danger for patients with normal kidney function. See supra Section A.2; *see also* Ex. A, *McGrath*, 2019 WL 2582530, at *6. Since Plaintiff pleads nothing to show Mallinckrodt could have changed OptiMARK's label, there are likewise no

allegations showing that Mallinckrodt could have foreseen Plaintiff's alleged injuries. *Id.* Accordingly, this claim must be dismissed.

2. Plaintiff's Claim for Breach of Express Warranty Fails for Lack of Pre-Suit Notice and Failure Identify Necessary Facts Regarding the Purported Warranty.

Plaintiff's claim for breach of express warranty (Count III) fails because Plaintiff does not allege that she provided pre-suit notice of her claim, as required by New Jersey Law. See Am. Compl. ¶¶ 206-211; *see also* N.J.S.A. § 12A:2-607(3)(a) ("Where a tender has been accepted [...] the buyer must within a reasonable time after [s]he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy."); *Hammer v. Vital Pharms., Inc.*, No. 11-4124, 2012 WL 1018842, at *10–11 (D.N.J. Mar. 26, 2012) (dismissing express and implied warranty claims where plaintiff failed to "plead that he provided the pre-litigation notice of breach," and confirming that based on section 12A:2-607(3)(a), the provision of such notice "is a condition precedent to filing any suit for breach of warranty" (internal quotation omitted)). Because Plaintiff failed to provide the requisite notice, Count III must be dismissed.

In addition, Plaintiff's breach of express warranty claim is insufficiently pled. Plaintiff's allegation is devoid of even the most basic information concerning the purported warranty—i.e., who made the warranty and when; where, in what form, and under what circumstances the warranty was made. *See* Am. Compl. ¶¶ 206-211.

Such plainly insufficient pleading cannot sustain her claim. *See, e.g.*, *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 602 (D.N.J. 2015) (dismissing plaintiff's warranty claim as "boilerplate" and noting that "[w]ho said what to whom, where, when, and how, are left unexpressed. There is no factual allegation in the Complaint that Sanofi ever made any identifiable, unapproved statements to [plaintiff] or her physician regarding the safety, effectiveness or proper applications of Sculptra."). Count III must be dismissed.

3. Plaintiff's Prayer for Punitive Damages Fails Under New Jersey Law.

Plaintiff's prayer for punitive damages fails under New Jersey law.[8] First, because Plaintiff's other claims fail, as set forth above, so too does her prayer for punitive damages. In New Jersey, there is no independent cause of action. *See O'Connor v. Harms*, 266 A.2d 605, 608 (App. Div. 1970) ("But where no compensatory damages are awarded, not even nominal, as in the instant case, there is an inference that the jury did not find a violation of a legal right, else it would have allowed at least nominal damages. A verdict for punitive damages alone

[8] In her original complaint, Plaintiff included an independent cause of action for punitive damages. *See* Compl. ¶¶ 175-179. Presumably recognizing the flaws relating to such a claim, Plaintiff has abandoned this independent cause of action in her Amended Complaint. *See generally* Am. Compl. However, L still contains a request for "punitive damages according to proof." *See id.* at 41. As explained herein, Plaintiff's request for punitive damages—however framed—fails under New Jersey law and must be dismissed.

suggests a punishment for malice, without more."). On this basis alone, Plaintiff's prayer for damages must be dismissed.

Second, the New Jersey Product Liability Act ("NJPLA") provides the ***exclusive*** remedy in a New Jersey products liability action. *See Repola v. Morbank Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991) (The NJPLA provides "the sole basis of relief under New Jersey Law available to consumers injured by an [allegedly] defective product."). This includes claims for punitive damages. *See Germanio v. Goodyear Tire & Rubber Co.*, 732 F. Supp. 1297, 1299 (D.N.J. 1990) (stating in a products liability action that "the punitive damages provision of the Product Liability Act directly applies to the present case."). In products liability actions involving an FDA-approved drug product, punitive damages are not available at all, as this Court has succinctly explained:

> The general rule under New Jersey Law is that punitive damages cannot be awarded in a products liability action based on an FDA-approved drug product. N.J.S.A. 2A:58C–5(c). While the PLA does provide an exception to this rule "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question ...", N.J.S.A. 2A:58C–5(c), the New Jersey Appellate Division has subsequently held that the exception is preempted by federal law. *McDarby v. Merck & Co., Inc.*, 401 N.J.Super. 10, 87–94, 949 A.2d 223 (App.Div.2008). ***It is undisputed that heparin is an FDA-approved drug product; thus, the Court finds that all claims for punitive damages stated in the first amended complaint are dismissed.***

Baker v. APP Pharm., LLC, No. CIV.A. 09-05725, 2010 WL 4941454, at *4 (D.N.J. Nov. 20, 2010) (emphasis added). *See also McDarby*, 401 N.J. Super. at 94 ("Because the punitive damages provisions of N.J.S.A. 2A:58C-5c impinge upon federal statute and regulation to the same extent that was recognized in *Buckman* […] we find the principles of implied preemption applied by the Court in *Buckman* to be applicable here."). GBCAs, including OptiMARK™, are undisputedly FDA-approved drug products, *see, e.g.*, Am. Compl. ¶¶ 126, 128, 155, and, thus, Plaintiff's prayer for punitive damages fails.

CONCLUSION

For the foregoing reasons, Mallinckrodt respectfully requests that this Court dismiss Plaintiff's Amended Complaint pursuant to Rules 8(a) and 12(b)(6).

Dated: September 17, 2019

Respectfully submitted,

By: */s/ Erin Leffler*

Erin (Loucks) Leffler
(NJ Bar No. 034092006)
SHOOK, HARDY & BACON L.L.P.
Two Commerce Square
2001 Market Street, Suite 3000
Philadelphia, PA 19103
Telephone: (215) 278-2555
Fax: (215) 278-2594
eleffler@shb.com

Devin K. Ross
Robert T. Adams
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108
Telephone: (816) 421-5547
Fax: (816) 421-5547
dkross@shb.com
rtadams@shb.com
Admitted Pro Hac Vice

COUNSEL FOR DEFENDANTS AMERISOURCEBERGEN CORPORATION AND AMERISOURCEBERGEN DRUG CORPORATION